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Practitioner's Docket No.

1540/140

AF/1614/\$
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Gordon, et al.

Application No.: 09/932,821

Group No.: 1614

Filed: August 17, 2001

Examiner: Bahar

For: Novel Formulation for Administering Therapeutic Lipophilic Molecules

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

**TRANSMITTAL OF SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
BEFORE MAILING DATE OF EITHER A FINAL ACTION
OR NOTICE OF ALLOWANCE (37 C.F.R. SECTION 1.97(c))**

NOTE: An information disclosure statement shall be considered by the Office if filed . . . before the mailing date of either (1) a final action under Section 1.113 or (2) a notice of allowance under Section 1.311, whichever occurs first, provided the statement is accompanied by either a statement as specified in paragraph (e) of Section 1.97 or the fee set forth in Section 1.17(p).

NOTE: "If a final action or notice of allowance is mailed in an application and later withdrawn, the application will be considered as not having had a final action or notice of allowance mailed for purposes of considering an information disclosure statement." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

NOTE: "If information submitted during the period set forth in 37 C.F.R. 1.97(c) with a certification is used in a new ground of rejection on unamended claims, the next Office action will not be made final since in this situation it is clear that applicant has submitted the information to the office promptly after it has become known and the information is being

CERTIFICATE OF MAILING/TRANSMISSION (37 C.F.R. SECTION 1.8(a))

I hereby certify that, on the date shown below, this correspondence is being:

MAILING

☒ deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

FACSIMILE

☐ [transmitted by facsimile to the Patent and Trademark Office (703) _____.

Date: _____ November 19, 2003

Signature

Barbara J. Carter, Ph.D.
(type or print name of person certifying)

(Transmittal of Information Disclosure Statement Before Mailing Date of Final Action or Notice of Allowance--page 1 of 3)

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submitted prior to a final determination on patentability by the Office. However, the information submitted with a certification can be used in a new ground of rejection and the next Office action made final, [i]f the new ground of rejection was necessitated by amendment of the application by applicant. Where the information is submitted during this period with a fee, the examiner may use the information submitted, e.g., printed publication or evidence of public use, and make the next Office action final whether or not the claims have been amended, provided that no other new ground of rejection which was not necessitated by amendment to the claims is introduced by the examiner. See MPEP 706.07(a). If a new ground of rejection is introduced that is neither necessitated by an amendment to the claims nor based on the information submitted with the fee set forth in 37 C.F.R. 1.17(p), the Office action shall not be made final." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

WARNING: "A petition for suspension of action to allow applicant time to submit an information disclosure statement will be denied as failing to present good and sufficient reasons, since 37 C.F.R. 1.97 provides adequate recourse for the timely submission of prior art for consideration by the examiner." Notice of July 6, 1992 (1141 O.G. 63).

TIME OF TRANSMITTAL OF ACCOMPANYING SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

1. The information disclosure statement transmitted herewith is being filed **after** three months of the filing date of this national application or the date of entry of the national stage as set forth in Section 1.491 in an international application or after the mailing date of the first Office action on the merits, whichever event occurred last but **before** the mailing date of either:

- (1) a final action under Section 1.113 or
- (2) a notice of allowance under Section 1.311,

whichever occurs first.

STATEMENT OR FEE

2. Accompanying this transmittal is

(check either A or B below)

A. ☐ a statement as specified in 37 C.F.R. Section 1.97(e).

OR

B. ☒ the fee set forth in 37 C.F.R. Section 1.17(p) for submission of an information disclosure statement under Section 1.97(c). (\$180.00).

FEE PAYMENT

(complete this item, if applicable)

3. Applicant elects the option to pay the fee set forth in 37 C.F.R. Section 1.17(p) for submission of an information disclosure statement under Section 1.97(c) (\$180.00).

Fee due \$ _____

METHOD OF PAYMENT OF FEE

4.

☒ Attached is a check in the amount of \$ 180.00.

☐ Charge Account No. _____ in the amount of \$ _____.

A duplicate of this request is attached.

If any additional fees are due, please charge Account #19-4972.

Reg. No. 52,703

Tel. No.: (617) 443-9292

Customer No.: 002101

01540/00140 279909.1



SIGNATURE OF PRACTITIONER

Barbara J. Carter, Ph.D.

(type or print name of practitioner)

125 Summer Street, 11th Floor

P.O. Address

Boston, MA 02110



Practitioner's Docket No.

1540/140

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent application

of _____

Inventor(s)

for _____

Title of invention

the specification of which is being transmitted herewith

OR

In re application of: Gordon, et al.

Application No.: 09/932,821

Group No.: 1614

Filed: August 17, 2001

Examiner: Bahar

For: Novel Formulation for Administering Therapeutic Lipophilic Molecules

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

(Information Disclosure Statement--page 1 of 7)

CERTIFICATION UNDER 37 C.F.R. SECTIONS 1.8(a) and 1.10*

(When using Express Mail, the Express Mail label number is mandatory;

Express Mail certification is optional.)

I hereby certify that, on the date shown below, this correspondence is being:

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37 C.F.R. SECTION 1.8(a)

37 C.F.R. SECTION 1.10*

[x] with sufficient postage as first class mail.

☐ as "Express Mail Post Office to Addressee"

Mailing Label No. _____ (mandatory)

TRANSMISSION

☐ transmitted by facsimile to the Patent and Trademark Office.

Signature

Date: November 17, 2003

Barbara J. Carter, Ph.D.

(type or print name of person certifying)

*WARNING:

Each paper or fee filed by "Express Mail" must have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. section 1.10(b).

"Since the filing of correspondence under section 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable C.F.R.e, requests for waiver of this requirement will not be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

NOTE: *"An information disclosure statement shall be considered by the Office if filed by the applicant:*

- (1) Within three months of the filing date of a national application;*
- (2) Within three months of the date of entry of the national stage as set forth in section 1.491 in an international application; or*
- (3) Before the mailing date of a first Office action on the merits, whichever event occurs last." 37 C.F.R. section 1.97(b).*

NOTE: *"Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section." 37 C.F.R. section 1.56(a).*

"Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) each inventor named in the application;*
- (2) each attorney or agent who prepares or prosecutes the application; and*
- (3) every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application." 37 C.F.R. section 1.56(c).*

NOTE: *The "duty as described in section 1.56 will be met so long as the information in question was cited by the Office or submitted to the Office in the manner prescribed by sections 1.97(b) - (d) and 1.98 before issuance of the patent." Notice of January 9, 1992, 1135 O.G. 13-25 at 17.*

WARNING: *"No information disclosure statement may be filed in a provisional application." 37 C.F.R. section 1.51(b).*

List of Sections Forming Part of This Information Disclosure Statement

The following sections are being submitted for this Information Disclosure Statement:

(check sections forming a part of this statement: disC.F.R.d unused sections and number pages consecutively)

1. ☒ Preliminary Statements
2. ☒ Forms PTO/SB/08A and 08B (substitute for Form PTO-1449)
3. ☐ Statement as to Information Not Found in Patents or Publications
4. ☐ Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted
5. ☐ Cumulative Patents or Publications
6. ☒ Copies of Listed Information Items Accompanying This Statement
7. ☐ Concise Explanation of Non-English Language Listed Information Items
 - 7A. ☐ EPO Search Report
 - 7B. ☐ English Language Version of EPO Search Report
8. ☐ Translation(s) of Non-English Language Documents
9. ☐ Concise Explanation of English Language Listed Information Items (Optional)
10. ☒ Identification of Person(s) Making This Information Disclosure Statement

(complete the following, if appropriate)

Sections _____, respectively, have been continued on ADDED PAGE(S).

NOTE : *"Once the minimum requirements are met, the examiner has an obligation to consider the information." Notice of April 20, 1992 (1138 O.G. 37-41, 37).*

Section 1. Preliminary statements

Applicants submit herewith patents, publications or other information, of which they are aware that they believe may be material to the examination of this application, and in respect of which, there may be a duty to disclose.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 C.F.R. section 1.97(g)), an admission that the information cited is, or is considered to be, material to patentability, or that no other material information exists.

The filing of this information disclosure statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13-25, at 25.

SECTION 2. FORMS PTO/SB/08A and 08B (formerly Form PTO-1449)**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: Gordon, et al. Attorney Docket: 1540/140
Serial No: 09/932,821 Art Group Unit: 1614
Date Filed: August 17, 2001 Examiner Name: Bahar
Invention: Novel Formulation for Administering Therapeutic Lipophilic Molecules

**LIST OF PATENTS AND PUBLICATIONS FOR
APPLICANT'S SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

U.S. PATENT DOCUMENTS					
Examiner Initials	Reference Number	Document Number	Issue Date	Inventor	Class/Subclass
	AL	US 5,554,601	09/10/96	Simpkins et al.	514/182
	AM	US 5,824,672	10/20/98	Simpkins et al.	514/182
	AN	US 5,843,934	12/01/98	Simpkins	514/182
	AO	US 5,859,001	01/12/99	Simpkins et al.	514/182
	AP	US 5,877,169	03/02/99	Simpkins	514/179
	AQ	US 5,972,923	10/26/99	Simpkins et al.	514/182
	AR	US 6,172,088	01/09/01	Simpkins et al.	514/340
	AS	US 6,197,833	03/06/01	Simpkins et al.	514/730
	AT	US 6,207,658	03/27/01	Simpkins et al.	514/182
	AU	US 6,319,914	11/20/01	Simpkins et al.	514/182
	AV	US 6,326,365	12/04/01	Simpkins et al.	514/179
	AW	US 6,339,078	01/15/02	Simpkins et al.	514/179
	AX	US 6,350,739	02/26/02	Simpkins et al.	514/182

OTHER DOCUMENTS			
Examiner Initials	Reference Number	Author	Title of Article, Title of Journal, Volume Number, Page Numbers, Date
	AY	Simpkins, et al.	"Alkyl Ether Modified Polycyclic Compounds Having a Terminal Phenol and Uses for Protection of Cells," US published application; 20020035100, A1, March 21, 2002, pgs. 1-17.

Examiner Signature: _____

Date Considered: _____

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation *if not* in conformance and not considered. Include copy of this form with next communication to applicant.

Section 6. Copies of Listed Information Items Accompanying This Statement

NOTE: 37 C.F.R. section 1.98(a)(2) requires that any information disclosure statement filed under section 1.97 shall include: "A legible copy of: (i) Each U.S. and foreign patent; (ii) Each publication or that portion which caused it to be listed; and (iii) All other information or that portion which caused it to be listed, except that no copy of a U.S. patent application need be included . . ."

NOTE: The wording in section 1.98(a)(2)(iii) makes it clear that the requirement to submit a copy of each item of information listed in an information disclosure statement does not apply to the citation of a U.S. patent application. Notice of January 9, 1992, 1135 O.G. 13-25, at 14.

Legible copies of all items listed in Forms PTO/SB/08A and 08B (substitute for Form PTO-1449) accompany this information statement.

(complete the following, if applicable)

☐ Exception(s) to above:

☐ Items in prior application, from which an earlier filing date is claimed for this application, as identified in Section 4.

☐ Cumulative patents or publications identified in Section 5.

Section 10. Identification of Person(s) Making This Information Disclosure Statement

The person making this certification is

(check each applicable item)

- (a) ☐ the inventor(s) who signs below

SIGNATURE OF INVENTOR

(type name of inventor who is signing)

- (b) ☐ an individual associated with the filing and prosecution of this application (37 C.F.R. section 1.56(c))

SIGNATURE OF INVENTOR

(type name of inventor who is signing)

- (c) ☒ the practitioner who signs below on the basis of the information:

(check each applicable item)

☐ supplied by the inventor(s).

☐ supplied by an individual associated with the filing and prosecution of this application. (37 C.F.R. section 1.56(c)).

☒ in the practitioner's file.

Reg. No.: 52,703

Tel. No.: (617) 443-9292

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01540/00140 279907.1



SIGNATURE OF PRACTITIONER

Barbara J. Carter, Ph.D.
(type or print name of practitioner)

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